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(54) Device for removing abnormal tissue from the human gastrointestinal tract

Vorrichtung zum Herausschneiden von abnormalem Gewebe im menschlichen Verdauungskanal
Dispositif pour ectomiser de tissus anormaux dans la voie gastro-intestinale humaine

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(56) References cited:

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US-A- 4 493 320
US-A- 5 336 222

US-A- 5 014 709

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Description**FIELD OF THE INVENTION**

[0001] This invention relates to a device for the removal of portions of the mucosa or submucosa from the digestive tract of a human being.

BACKGROUND OF THE INVENTION

[0002] Diagnostic and therapeutic gastrointestinal endoscopy is commonly used to gain access to the digestive tract for the purpose of observing and removing tissue. Common endoscopic therapeutic instruments include cutting, ablating and unclogging through various known mechanisms.

[0003] Techniques for obtaining tissues for biopsies include the use of forceps (with or without coagulation), snares or, for cytologic examination, needles and brushes. While these techniques permit the accomplishment of many diagnostic and/or therapeutic goals, in some instances they are inadequate. For example, there currently exists no satisfactory device for the removal of flat malignant mucosal lesions or lesions in the submucosa. On some occasions, deep specimens are required for a diagnosis (e.g. lymphoma or Menetrier's disease) in which cases current procedures are limited. Techniques such as "lift and cut" resection and polypectomy after a submucosal injection of a saline or glucose solution have been used but these procedures are not always successful because on some occasions the tissue does not elevate and in others the injection may actually flatten the area making tissue removal more difficult. These procedures, known as endoscopic mucosectomy are becoming increasingly popular, particularly in Japan where early gastric cancer is common.

[0004] Elastic band ligation is a process used to control bleeding in portions of the gastrointestinal tract. For example, in the treatment of hemorrhoids or esophageal varices, mucosal and submucosal tissue may be entrapped by an elastic ligature causing strangulation, sloughing off and eventual fibrosis of the lesion. Steigmann U.S. patent No. 4,735,194 illustrates a single band ligating instrument which has achieved commercial success as the Steigmann-Goff Clearvue™ single band ligator.

[0005] Ligating instruments such as the Steigmann-Goff Clearvue™ ligator are useful in the treatment of esophageal varices and hemorrhoids in which veins that are bleeding or may tend to bleed are isolated by ligation bands; however, ligation has not previously been used for the purpose of treating cancerous and precancerous conditions that may exist in the gastrointestinal tract, in which the abnormal tissue tends to lie flat and is not readily subject to conventional ligation procedures.

[0006] U.S. Patent No. 4,493,320 relates to a bipolar electrocautery snare for use with endoscopic surgical instruments. The snare includes a unitary double lumen

member that includes a septum or divider extending along its length which forms an electrically insulating barrier between the two snare wires.

[0007] U.S. Patent No. 5,336,222 discloses an integrated catheter assembly that enables a physician to select among hemostatic and injection therapies.

[0008] U.S. Patent No. 5,014,709 discloses a method and apparatus for high resolution holographic recordation and microscopic examination of an holographic image of biological tissue.

[0009] Early esophageal cancer is an important problem in many parts of the world. With appropriate screening tests, the diagnosis can be made when the disease is limited to the mucosa or even in a premalignant phase. There are known procedures for the destruction of early esophageal cancer (e.g. laser photocoagulation) but there is an existing need for a device which will permit the efficient and complete removal of tissue from patients with early esophageal cancer and in the other conditions described above.

[0010] It is an object of this invention to provide an improved device for the removal of cancerous and precancerous tissue within the gastrointestinal tract.

SUMMARY OF THE INVENTION

[0011] The device according to the invention comprise a suction channel extending along a length of the endoscope for applying suction to the abnormal tissue to pull the abnormal tissue into a ligator at the distal end of the endoscope, further an inner tube axially disposed at a distal end of the endoscope for applying a ligation band to a base of the abnormal tissue within the ligator to form a polyp consisting of the abnormal tissue, and an electrosurgical snare including an outer sheath and a wire loop forming a loop which lies in a plane at approximately a right angle to the longitudinal axis of the sheath for severing the polyp.

BRIEF DESCRIPTION OF THE DRAWINGS**[0012]**

Fig. 1 is a longitudinal view in partial section of the endoscopic ligating instrument illustrating certain features in accordance with this invention,

Figs 2-8 are schematic representations of a device illustrating certain features in accordance with the preferred embodiment of the invention; and

Fig. 9 is a cross-sectional view of the distal end of a snare in accordance with the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0013] The invention relates to a mucosectomy device which can be applied to any part of the gastrointestinal tract, including the esophagus, the stomach and the small intestine. For purposes of explanation, the invention is described in its preferred embodiment for removal of a mucosal lesion in the esophagus. In practicing the invention, it is contemplated that a conventional ligator and snare may be used although in a preferred embodiment, and as described in detail below, a specially constructed snare is used.

[0014] Fig. 1 illustrates a flexible endoscope 10 equipped with a ligator of the type which may be used to practice the invention. Endoscope 10 includes a suction channel 11 and fiberoptics illumination channel 12, both exiting at terminal 13 which is connected to a control box (not shown) for supplying suction and illumination. Eyepiece 14 provides means for viewing the ligation procedure either directly or by video camera and subsequent projection onto a video monitor. Trip wire 15, located in biopsy channel 16, is equipped with weighted handle 17, and is fastened to inner tube 18 at notch.

[0015] Ligating ring 20 is mounted on inner tube 18 at notch 19. Ligating ring 20 is mounted on inner tube 18, which is positioned within outer tube 21. Outer tube 21 is fastened securely to endoscope 10 by means of threaded connection 22.

[0016] In utilization of the instrument, elastic ring 20 is mounted over the forward end of the tube 18. Trip wire 15 exiting via biopsy channel 16 is attached to notch 19 at the rearward end of tube 18 and the assembly is placed inside tube 21, which had been securely attached to endoscope 10. Tube 18 is seated within tube 21 with ring 20 protruding just beyond the end of the tube 21, as shown in Fig. 1. Trip wire 15 exiting at the rearward end of endoscope 10 is held in tension by weighted handle 17.

[0017] After placement of an endoscopic overtube in the patient, the instrument is introduced into the alimentary tract. The target lesion is visualized and the instrument is advanced under direct vision until tube 18 surrounds the intended target. Once full 360° contact is made, suction is activated drawing the lesion into tube 18. When the lesion is totally within tube 18, trip wire 15 is pulled, ring 20 slides off and becomes securely fixed around the base of the target lesion.

[0018] Figures 2-8 show how a mucosectomy may be performed in the esophagus in accordance with the invention. Endoscope 10 is introduced into the esophagus at a position adjacent the area to be resected (Fig. 2). After the endoscope is in position, a spray catheter 30 (Fig. 3) is introduced through suction channel 11 and the area in question 31 stained, for example, with Lugol's Iodine which is a conventional stain that will turn brown when it contacts tissue cells containing glycogen. Cancerous and precancerous cells do not contain glycogen

and therefore do not accept the stain. In this way the abnormal tissue 31 can be identified endoscopically. After the section in question has been stained, the spray catheter 30 is removed and an injection catheter 32 (Fig. 4) introduced through suction channel 11 of the endoscope. A saline solution (for example, 0,9% NaCl) is injected into the stained area to elevate it from the surrounding tissue of the esophagus (Fig. 5.). Other materials such as glucose solution may be used to elevate the abnormal area.

[0019] The injection catheter 32 and the endoscope 10 are removed from the patient's esophagus and a single fire ligator secured to the distal end of the endoscope, as shown in Fig. 1. The endoscope is then reintroduced into the patient's esophagus so that the distal end of the ligator is adjacent the elevated abnormal area (Fig. 6).

[0020] Suction is applied through suction channel 11 to pull the abnormal area into the ligator. The trip wire 15 is then pulled to apply a ligator band 18 around the base of the abnormal area so that when the ligator is removed, a banded mushroom-like polyp 34 is formed (Fig. 7).

[0021] The endoscope 10 is removed from the patient and the ligator is detached from the endoscope. The endoscope again is inserted into the esophagus. When the banded "polyp" is in view, a conventional snare comprising a wire loop 36 and sheath 38 may be introduced through the biopsy channel 16 of the endoscope. The snare is positioned so that the wire loop envelopes the artificially created polyp (Fig. 8). When the wire loop 36 is pulled into the sheath 38 the polyp is cut from the esophagus and cauterised. The polyp may be withdrawn physically by the snare through the endoscope or released into the patient's gastrointestinal tract.

[0022] The snare used in Fig. 8 may be conventional, for example, a monopolar electrosurgery device which simultaneously cuts and cauterises tissue, such as a polyp or the like. Typically, such snares comprise a wire loop which may be retracted into a sheath causing the loop tighten around the polyp. The application of voltage simultaneously severs the polyp and cauterises the wound.

[0023] The distal end of a snare especially adapted for use with the invention is shown in Fig. 9. The outer sheath of the snare is shown at 38 and the wire loop at 36. A conductive pull wire 29 is attached to the loop 36 by a connector 37 which may be crimped and soldered to adjacent ends of wire 39 and loops 36. Unlike conventional snares, the free end of the wire 36 is connected to a small ferrule 40 which is attached, for example, by adhesive, to the distal end of the sheath 38. The wire loop 36 may be soldered to the ferrule 40. With this arrangement, the loop 36 may be permanently bent at points so that when the wire 39 is pushed distally (as shown in Fig. 9), the loop which is formed lies in a plane at an angle close to ninety degrees with respect to the longitudinal axis of sheath 38. In contrast to convention-

al snares in which the loop when extended lies in the same plane as the longitudinal axis of the sheath, the arrangement of Fig. 9 is particularly useful in removing a "polyp" formed by the use of the ligator of Fig. 1 as represented in Fig. 6 and 7. The handle of the snare at its proximal end may be conventional handle of the snare at its proximal end may be conventional and, therefore, is not illustrated.

[0024] Having thus described a preferred embodiment of the present invention, it is to be understood that the above described is merely illustrative of the principles of the present invention, and that other devices may be devised by those skilled in the art without departing from the scope of the appended claims.

LIST OF REFERENCES:

[0025]

- | | |
|----|----------------------|
| 10 | flexible endoscope |
| 11 | suction channel |
| 12 | illumination channel |
| 13 | terminal |
| 14 | eyepiece |
| 15 | trip wire |
| 16 | biopsy channel |
| 17 | handle |
| 18 | inner tube |
| 19 | notch |
| 20 | ligating ring |
| 21 | outer tube |
| 22 | connection |
| 30 | spray catheter |
| 31 | area in question |
| 32 | injection catheter |
| 34 | mushroom-like polyp |
| 36 | wire loop |
| 37 | connector |
| 38 | sheath |
| 39 | pull wire |
| 40 | ferrule |

Claims

1. A device inserted into an endoscope for removing abnormal tissue from the gastrointestinal tract of a patient, comprising:

a suction channel (11) extending along a length of the endoscope (10) for applying suction to the abnormal tissue to pull the abnormal tissue into a ligator at the distal end of the endoscope (10),

an inner tube (18) axially disposed at a distal end of the endoscope (10) for applying,

a ligation band (20) to a base of the abnormal tissue within the ligator to form a polyp (34) consisting of the abnormal tissue, and

an electrosurgical snare including an outer sheath (38) and a wire loop (36) forming a loop (36) which lies in a plane at approximately a right angle to the longitudinal axis of the sheath (38) for severing the polyp (34).

2. A device according to claim 1, further comprising:

an injection catheter (32) for raising abnormal tissue before pulling of the tissue into the ligator.

3. A device according to claim 1, further comprising:

a removable spray catheter (30) axially disposed with the endoscope (10) for applying a stain to the abnormal tissue prior to ligation.

Patentansprüche

1. Vorrichtung, die in ein Endoskop eingesetzt wird, zum Herausschneiden von abnormalem Gewebe im Verdauungskanal eines Patienten, bestehend aus einem Unterdruckkanal (11), der sich über einen Längenabschnitt des Endoskops (10) erstreckt und zum Anlegen eines Unterdruckes an das abnormale Gewebe dient, wodurch das abnormale Gewebe in den am distalen Ende des Endoskops (10) angeordneten Ligator gezogen wird, einem Innenrohr (18), das axial an einem distalen Ende des Endoskops (10) angeordnet ist, zum Applizieren eines Ligaturbandes (20) auf eine Basis des abnormalen Gewebes innerhalb des Ligators zur Bildung eines Polypen (34) aus abnormalem Gewebe und einer elektrochirurgischen Schlinge mit einem äußeren Mantel (38) und einer Drahtschlaufe (36), die eine Schleife (36) bildet, welche in einer ungefähr rechtwinklig zur Längssachse des zum Herausschneiden des Polypen (34) dienenden Mantels (38) verlaufenden Ebene liegt.

2. Vorrichtung gemäß Anspruch 1, weiterhin bestehend aus einem Injektionskatheter (32) zum Erfassen von abnormalem Gewebe, bevor dieses in den Ligator gezogen wird.

3. Vorrichtung gemäß Anspruch 1, weiterhin bestehend aus

hend aus
einem axial im Endoskop (10) angeordneten her-
ausziehbaren Sprühkatheter (30) zum Färben des
abnormalen Gewebes vor der Ligatur.

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Revendications

- 1. Dispositif, inséré dans un endoscope afin d'ectomiser des tissus anormaux dans la voie gastro-intestinale d'un patient et, comprenant:**

Un conduit d'aspiration (11) s'étendant le long de l'endoscope (10) et permettant d'exercer une aspiration sur les tissus anormaux pour tirer ces derniers de sorte qu'ils pénètrent dans un ligatureur situé à l'extrémité distale de l'endoscope (10),

Un tube intérieur (18) disposé axialement à une extrémité distale de l'endoscope (10) afin d'appliquer

Un ruban de ligature (20) à une base des tissus anormaux situés à l'intérieur du ligatureur, afin de former un polype (34) composé des tissus anormaux, et

un noeud coulant électro-chirurgical comprenant un fourreau extérieur (38) et un fil (36) formant boucle (36) et reposant sur un plan approximativement perpendiculaire à l'axe longitudinal du fourreau (38) pour sectionner le polype (34).

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- 2. Dispositif selon la revendication 1, comprenant en outre:**

Un cathéter d'injection (32) servant à soulever des tissus anormaux avant de tirer ces tissus jusqu'à dans le ligatureur.

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- 3. Dispositif selon la revendication 1, comprenant en outre:**

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Un cathéter de pulvérisation (30) amovible, disposé axialement avec l'endoscope (10) et servant à appliquer une marque sur les tissus anormaux avant leur ligaturation.

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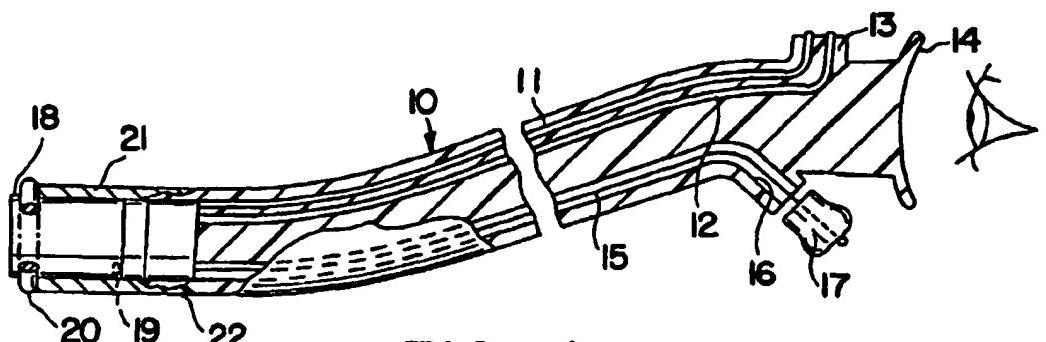


FIG. 1

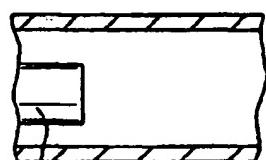


FIG. 2

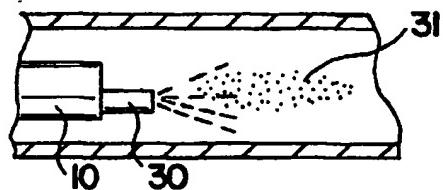


FIG. 3

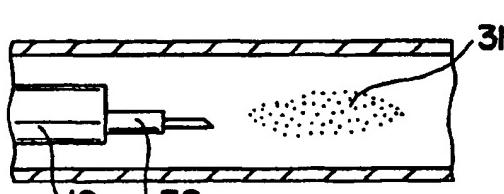


FIG. 4

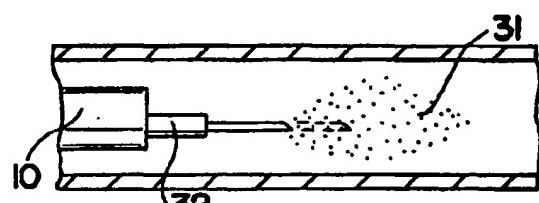


FIG. 5

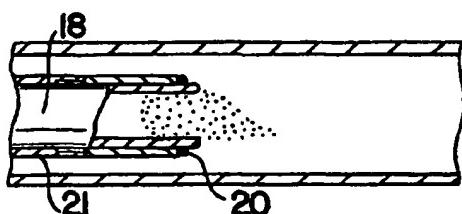


FIG. 6

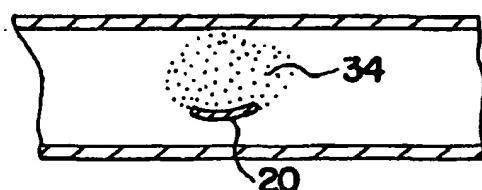


FIG. 7

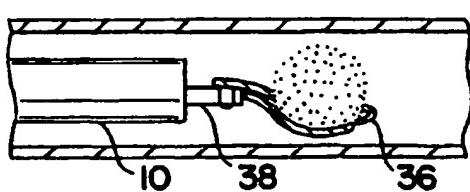


FIG. 8

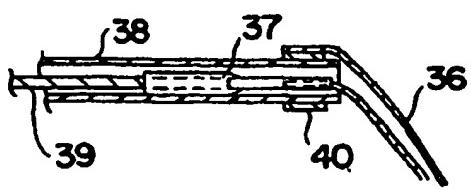


FIG. 9